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# TRANSMITTAL FORM

to be used for all correspondence after initial filing)

Application Number	10/010,114
Filing Date	11/13/2001
First Named Inventor	Raymond H. Boutin
Group Art Unit	1632
Examiner Name	D. Crouch
Attorney Docket Number	AHP1CUSA

Total Number of Pages in This Submission 17

## ENCLOSURES (check all that apply)

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<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment / Reply	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
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<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Cathy A. Kodroff, Esquire Howson and Howson
Signature	<i>Cathy A. Kodroff</i>
Date	2-5-2002

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PATENT TRADEMARK OFFICE

AHP1CUSA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Raymond H. Boutin

Appln. No. 10/010,114

Filed: November 13, 2001

For: MULTIFUNCTIONAL MOLECULAR  
COMPLEXES FOR GENE TRANSFER  
TO CELLS

Assistant Commissioner for Patents  
Washington, DC 20231



) Group Art Unit: 1632

) Examiner: D. Crouch

) February 5, 2002

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INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants submit to the Examiner the attached Form PTO/SB/08A/B document listing and this paper pursuant to 37 CFR §1.56 and § 1.97-1.98. Form PTO/SB/08A/B and this paper identify documents previously cited in the parent application, U.S. Patent Application No. 09/425,597, filed October 22, 1999, currently pending.

According to 37 CFR § 1.98(d), Applicants have not enclosed copies of any U.S. patents, publications or other documents listed herein, which listed items were previously cited by or submitted to the United States Patent and Trademark Office in parent U. S. Patent Application No. 09/425,597, filed October 22, 1999, (pending). The parent patent application is relied upon herein for an earlier priority date under 35 USC §120.

CERTIFICATE UNDER 37 CFR §1.8(a)

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Signature Debra N. Gerstemeier

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This Information Disclosure Statement is submitted within three months of the filing date of this application, and prior to receipt of an Office Action on the merits. Therefore, no fees are believed due. However, the Director of the U. S. Patent and Trademark Office is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing, or during prosecution of this application to Deposit Account No. 08-3040.

The Examiner is respectfully requested to consider the documents identified in this paper and in the attached Form PTO/SB/08A/B during the course of the examination of this application.

Respectfully submitted,

HOWSON AND HOWSON  
Attorneys for the Applicants

By

  
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Substitute for Form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Complete if Known			
		Application Number	10/010,114		
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		First Named Inventor	Raymond H. Boutin		
		Group Art Unit	1632		
		Examiner Name	D. Crouch		
Sheet	1	of	14	Attorney Docket Number	AHP1CUSA

U.S. PATENT DOCUMENTS						
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	5,108,921	B1	P. Low	04/28/1992	
	AB	5,166,320	B1	G. Wu	11/24/1992	
	AC	5,171,678	B1	J. Behr	12/15/1992	
	AD	5,283,185	B1	R. Epand	02/01/1994	
	AE	5,614,503	B1	N. Chaudhary	03/25/1997	

FOREIGN PATENT DOCUMENTS								
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		Office <sup>2</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	AL	WO	WO86/00930	A1	H. Robinson	02/13/1986		
	AM	WO	WO90/11092	A1	P. Felgner	10/04/1990		
	AN	WO	WO90/12095	A1	P. Low	10/18/1990		
	AO	WO	WO90/12096	A1	P. Low	10/18/1990		
	AP	WO	WO91/16024	A1	P. Felgner	10/31/1991		
	AQ	WO	WO92/06180	A1	G. Wu	04/16/1992		

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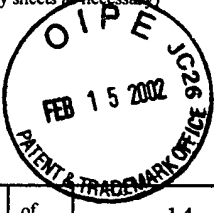
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	AF	5,650,096	B1	D. Harris	07/22/1997	
	AG	5,719,131	B1	D. Harris	02/17/1998	
	AH	5,747,471	B1	C. Siegel	05/05/1998	
	AI	5,767,099	B1	D. Harris	06/16/1998	
	AJ	5,783,565	B1	C. Siegel	07/21/1998	

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	AAL	WO	WO93/19768	A1	F. Szoka	10/14/1993		
	AAM	WO	WO93/24640	A1	R. Debs	12/09/1993		

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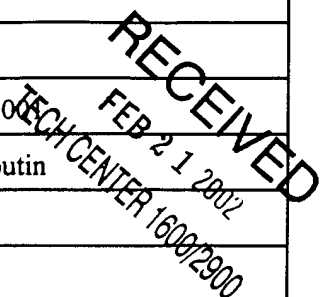
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	AK	5,840,710	B1	E. Lee	11/24/1998	
	AAA	5,910,487	B1	N. Yew	06/08/1999	
	AAB	5,912,239	B1	C. Siegel	06/15/1999	
	AAC	5,925,628	B1	E. Lee	07/20/1999	
	AAD	5,935,936	B1	A. Fasbender	08/19/1999	

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	AAE	5,942,634	B1	C. Siegel	08/24/1999	
	AAF	5,948,767	B1	R. Scheule	09/07/1999	
	AAG	5,981,273	B1	D. Curiel	11/09/1999	

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			Examiner Name	D. Crouch	
Sheet	5	of	14	Attorney Docket Number	AHP1CUSA

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiners Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AR	P. ATANASIU et al, "Virologie - Production de tumeurs chez le Hamster par inoculation d'acide desoxyribonucleique extrait de cultures de tissus infectees par le virus du polyome", Academie des Sciences (Paris), 254:4228-4230 (1962)	
	AS	F. BARTHEL et al, "Laboratory Methods, Gene Transfer Optimization with Lipospermine-Coated DNA", DNA and Cell Biology, 12(6):553-560 (1993)	
	AT	H. BASU et al, "Effects of Variation in the Structure of Spermine on the Association with DNA and the Induction of DNA Conformational Changes", Biochem. J., 269:329-334 (1990)	
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	AV	J-P. BEHR, Gene Transfer with Synthetic Cationic Amphiphiles: Prospects for Gene Therapy", Bioconjugate Chem., 5:382-389 (1994)	
	AW	P. BERMAN, "Efficacy of Recombinant Glycoprotein D Subunit Vaccines on the Development of Primary, Recurrent, and Latent Genital Infections with Herpes Simplex Virus Type 2 in Guinea Pigs", J. Infect. Dis., 157(5):897-902 (May, 1988)	
	AX	C. BENNETT et al, "Cationic Lipids Enhance Cellular Uptake and Activity of Phosphorothioate Antisense Oligonucleotides", Molecular Pharmacology, 41:1023-1033 (1992)	
	AY	H. BLAU et al, "Molecular Medicine, Gene Therapy - A Novel Form of Drug Delivery", New Engl. J. Med., 333(18):1204-1207 (November 2, 1995)	
Examiner Signature			Date Considered

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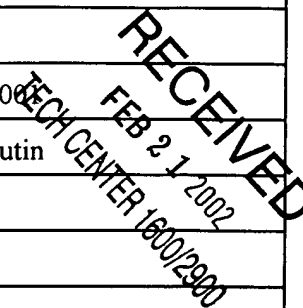
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	AZ	J. BODMER et al, "Carrier Potential of Glycoproteins", Methods in Enzymology, 112:298-306 (1985)	
	AAR	E. BONFILS et al, "Uptake by Macrophages of a Biotinylated Oligo- $\alpha$ -deoxythymidylate by Using Mannosylated Streptavidin", Bioconj. Chem., 3:277-284 (1992)	
	AAS	E. BONFILS et al, "Drug Targeting: Synthesis and Endocytosis of Oligonucleotide-Neoglycoprotein Conjugates", Nucleic Acids Research, 20(17):4621-4629 (1992)	
	AAT	V. CHAUDHARY et al, "A Rapid Method of Cloning Functional Variable-Region Antibody Genes in Escherichia coli as Single-Chain Immunotoxins", Proc. Natl. Acad. Sci. USA, 87:1066-1070 (February, 1990)	
	AAU	C-J. CHU et al, "Efficiency of Cytoplasmic Delivery by pH-Sensitive Liposomes to Cells in Culture", Pharmaceutical Research, 7(8):824-834 (1990)	
	AAV	G. CITRO et al, "Inhibition of Leukemia Cell Proliferation by Receptor-Mediated Uptake of c-myb Antisense Oligodeoxynucleotides", Proc. Natl. Acad. Sci. USA, 89:7031-7035 (August, 1992)	
	AAW	COHEN, "Oligonucleotides: Antisense Inhibitors of Gene Expression", CRC Press, Inc., Boca Raton, FL (1989)	
	AAX	C. CONNELLY et al, "Polyamines Eliminate an Extreme Size Bias Against Transformation of Large Yeast Artificial Chromosome DNA", Genomics, 10:10-16 (1991)	
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	AAY	M. COTTEN et al, "High-Efficiency Receptor-Mediated Delivery of Small and Large 48 kilobase Gene Constructs Using the Endosome-Disruption Activity of Defective or Chemically Inactivated Adenovirus Particles", Proc. Natl. Acad. Sci. USA, 89:6094-6098 (July, 1992)		
	AAZ	D. CURIEL et al, "Adenovirus Enhancement of Transferrin-Polylysine-Mediated Gene Delivery", Proc. Natl. Acad. Sci. USA, 88:8850-8854 (October, 1991)		
	BR	S. EDGINGTON, "Ribozymes: Stop Making Sense", Biotechnology, 10:256-262 (March, 1992)		
	BS	M. ELOFSSON et al, "Solid-Phase Synthesis and Conformational Studies of Glycosylated Derivatives of Helper-T-Cell Immunogenic Peptides from hen-egg Lysozyme", Carbohydrate Research, 246:89-103 (1993)		
	BT	J. FELGNER et al, "Enhanced Gene Delivery and Mechanism Studies with a Novel Series of Cationic Lipid Formulations", J. Biol. Chem., 269(4):2550-2561 (January, 1994)		
	BU	P. FELGNER et al, "Cationic Liposome-Mediated Transfection", Nature, 337:387-388 (January, 1989)		
	BV	L. GAO et al, "Direct In Vivo Gene Transfer to Airway Epithelium Employing Adenovirus-Polylysine-DNA Complexes", Human Gene Therapy, 4:17-24 (1993)		
	BW	H. GERSHON et al, "Mode of Formation and Structural Features of DNA-Cationic Liposome Complexes Used for Transfection", Biochemistry, 32:7143-7151 (1993)		
	BX	J. HAENSLER et al, "Polyamidoamine Cascade Polymers Mediate Efficient Transfection of Cells in Culture", Bioconjugate Chem., 4:372-379 (1993)		
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	BY	J. HAENSLER et al, "Synthesis and Characterization of a Trigalactosylated Bisacridine Compound to Target DNA to Hepatocytes", Bioconjugate Chem., 4:85-93 (1993)		
	BZ	M. HOWELL et al, "Limited T-Cell Receptor $\beta$ -chain Heterogeneity Among Interleukin 2 Receptor-Positive Synovial T Cells Suggests a Role for Superantigen in Rheumatoid Arthritis", Proc. Natl. Acad. Sci. USA, 88:10921-10925 (December, 1991)		
	BBR	B. HUCKETT et al, "Evidence for Targeted Gene Transfer by Receptor-Mediated Endocytosis, Stable Expression Following Insulin-Directed Entry of NEO into HepG2 Cells", Biochemical Pharmacology, 40(2):253-263 (1990)		
	BBS	M. ISRAEL et al, "Biological Activity of Polyoma Viral DNA in Mice and Hamsters", J. Virol., 29:990-996 (March, 1979)		
	BBT	J. JONES et al, "Cell Fusion Induced by the Murine Leukemia Virus Envelope Glycoprotein", J. Virol., 67(1):67-74 (January, 1993)		
	BBU	R. JULIANO et al, "Interaction of Polynucleotides with Cultured Mammalian Cells", Experimental Cell Research, 73:3-12 (1972)		
	BBV	A. KABANOV et al, "Efficient Transformation of Mammalian Cells Using DNA Interpolyelectrolyte Complexes with Carbon Chain Polycations", Bioconjugate Chem., 4:448-454 (1993)		
	BBW	KABAT et al, "1987 Sequence of Proteins of Immunological Interest U.S. Department of Health and Human Services", Bethesda, MD		
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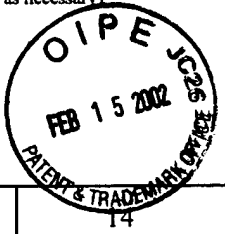
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	BBX	K. KAWAGUCHI et al, "Differential Uptake of D-Glucosyl-neoglycoproteins by Isolated Rat Hepatocytes", J. Biol. Chem., 256(5):2230-2234 (March, 1981)		
	BBY	K. KONO et al, "Fusion Activity of an Amphiphilic Polypeptide Having Acidic Amino Acid Residues: Generation of Fusion Activity by $\alpha$ -helix Formation and Charge Neutralization", Biochimica et Biophysica Acta., 1164:81-90 (1993)		
	BBZ	C. LEAMON et al, "Delivery of Macromolecules into Living Cells: A Method that Exploits Folate Receptor Endocytosis", Proc. Natl. Acad. Sci. USA, 88:5572-5576 (July, 1991)		
	CR	J. LEAR et al, "Membrane Binding and Conformation Properties of Peptides Representing the NH <sub>2</sub> Terminus of Influenza HA-2", J. Biol. Chem., 262(14):6500-6505 (May, 1987)		
	CS	Y. LEE, "Synthesis of Some Cluster Glycosides Suitable for Attachment to Proteins or Solid Matrices", Carbohydrate Research, 67:509-514 (1978)		
	CT	Y. LEE et al, "Binding of Synthetic Oligosaccharides to the Hepatic Gal/GalNAc Lectin", J. Biol. Chem., 258(1):199-202 (January, 1983)		
	CU	J-Y. LEGENDRE et al, "Delivery of Plasmid DNA into Mammalian Cell Lines Using pH-Sensitive Liposomes: Comparison with Cationic Liposomes", Pharmaceutical Research, 9(10):1235-1242 (1992)		
	CV	J-Y. LEGENDRE et al, "Cyclic Amphipathic Peptide - DNA Complexes Mediate High-Efficiency Transfection of Adherent Mammalian Cells", Proc. Natl. Acad. Sci. USA, 90:893-897 (February, 1993)		
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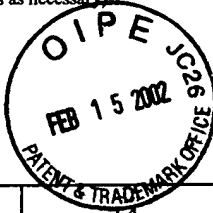
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	CW	R. LEVENTIS et al, "Interactions of Mammalian Cells with Lipid Dispersions Containing Novel Metabolizable Cationic Amphiphiles", Biochimica et Biophysica Acta., 1023:124-132 (1990)		
	CX	H. LODISH, "Recognition of Complex Oligosaccharides by the Multi-subunit Asialoglycoprotein Receptor", TIBS, 16:374-377 (October, 1991)		
	CY	J-P. LOEFFLER et al, "Gene Transfer into Primary and Established Mammalian Cell Lines with Lipopolyamine-Coated DNA", Meth. Enzymol., 217:599-618 (1993)		
	CZ	K. MACK et al, "Cationic Lipid Enhances in Vitro Receptor-Mediated Transfection", Am. J. Med. Sci., 307(2):138-143 (February, 1994)		
	CCR	R. MALONE et al, "Cationic Liposome-Mediated RNA Transfection", Proc. Natl. Acad. Sci. USA, 86:6077-6081 (August, 1989)		
	CCS	E. MAYHEW et al, "Interaction of Polynucleotides with Cultured Mammalian Cells, II. Cell Surface Charge Density and RNA Uptake", Experimental Cell Research, 77:409-414 (1973)		
	CCT	P. MIDOUX et al, "Specific Gene Transfer Mediated by Lactosylated Poly-L-Lysine into Hepatoma Cells", Nucleic Acids Research, 21(4):871-878 (1993)		
	CCU	R. MULLIGAN, "The Basic Science of Gene Therapy", Science, 260:926-932 (May, 1993)		
	CCV	S. NAGARAJAN et al, "Chemistry of Naturally Occurring Polyamines. 9. Synthesis of Spermidine and Spermine Photoaffinity Labeling Reagents", J. Org. Chem., 50(26):5735-5737 (1985)		
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	CCW	J. NIEVA et al, "Interaction of the HIV-1 Fusion Peptide with Phospholipid Vesicles: Different Structural Requirements for Fusion and Leakage", Biochemistry, 33:3201-3209 (1994)		
	CCX	J. OKSENBERG et al, "Limited Heterogeneity of Rearranged T-Cell Receptor Va Transcripts in Brains of Multiple Sclerosis Patients", Nature, 345:344-346 (May, 1990)		
	CCY	S. ORKIN et al, "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy", NIH Review Panel on Gene Therapy, (December 7, 1995)		
	CCZ	A. OSOL, Remington's Pharmaceutical Sciences		
	DR	X. PALIARD et al, "Evidence for the Effects of a Superantigen in Rheumatoid Arthritis", Science, 253:325-329 (July, 1991)		
	DS	G. PAOLELLA et al, "Nuclease Resistant Ribozymes with High Catalytic Activity", EMBO J., 11(5):1913-1919 (1992)		
	DT	J. PERALES et al, "Gene Transfer in vivo: Sustained Expression and Regulation of Genes Introduced into the Liver by Receptor-Targeted Uptake", Proc. Natl. Acad. Sci. USA, 91:4086-4090 (April, 1994)		
	DU	P. PINNADUWAGE et al, "A Positively Charged Liposome Used for the Efficient Delivery of DNA to Mouse L-Cells, an Alternative to Lipofectin", Biophysical Journal, 55:341a (1989) Abstract No. Tu-Pos232		
	DV	C. PLANK et al, "Gene Transfer into Hepatocytes Using Asialoglycoprotein Receptor Mediated Endocytosis of DNA Complexed with an Artificial Tetra-Antennary Galactose Ligand", Bioconjugate Chem., 3:533-539 (1992)		
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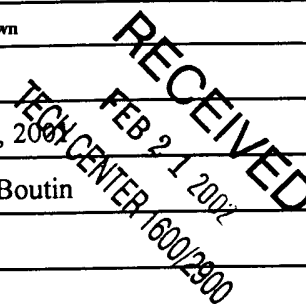
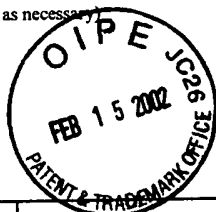
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	DW	G. PLUM et al, "Condensation of DNA by Trivalent Cations. 2. Effects of Cation Structure", Biopolymers, 30:631-643 (1990)		
	DX	J. ROSE et al, "A New Cationic Liposome Reagent Mediating Nearly Quantitative Transfection of Animal Cells", BioTechniques, 10(4):520-525 (1991)		
	DY	J. SAMBROOK et al, "Molecular Cloning: A Laboratory Manual", Cold Spring Harbor (1989)		
	DZ	R. SCHLEGEL et al, "A Synthetic Peptide Corresponding to the NH <sub>2</sub> Terminus of Vesicular Stomatitis Virus Glycoprotein is a pH-Dependent Hemolysin", J. Biol. Chem., 259(8):4691-4694 (April, 1984)		
	DDR	N. SCHMID et al, "Location of Spermine and Other Polyamines on DNA as Revealed by Photoaffinity Cleavage with Polyaminobenzenediazonium Salts", Biochemistry, 30:4357-4361 (1991)		
	DDS	J. SMITH et al, "Liposomes as Agents of DNA Transfer", Biochimica et Biophysica Acta., 1154:327-340 (1993)		
	DDT	S. SOUKCHAREUN et al, "Preparation and Characterization of Antisense Oligonucleotide-Peptide Hybrids Containing Viral Fusion Peptides", Bioconjugate Chem., 6:43-53 (1995)		
	DDU	L. STAMATATOS et al, "Interactions of Cationic Lipid Vesicles with Negatively Charged Phospholipid Vesicles and Biological Membranes", Biochemistry, 27:3917-3925 (1988)		
	DDV	N. SUBBARAO et al, "pH-Dependent Bilayer Destabilization by an Amphipathic Peptide", Biochemistry, 26:2964-2972 (1987)		
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	DDX	E. WAGNER et al, "Transferrin-Polycation Conjugates as Carriers for DNA Uptake into Cells", Proc. Natl. Acad. Sci. USA, 87:3410-3414 (May, 1990)	
	DDY	E. WAGNER et al, "Coupling of Adenovirus to Transferrin-Polylysine/DNA Complexes Greatly Enhances Receptor-Mediated Gene Delivery and Expression of Transfected Genes", Proc. Natl. Acad. Sci. USA, 89:6099-6103 (July, 1992)	
	DDZ	E. WAGNER et al, "Influenza Virus Hemagglutinin HA-2 N-Terminal Fusogenic Peptides Augment Gene Transfer by Transferrin-Polylysine-DNA Complexes: Toward a Synthetic Virus-Like Gene-Transfer Vehicle", Proc. Natl. Acad. Sci. USA, 89:7934-7938 (September, 1992)	
	ER	J. WHITE et al, "Membrane Fusion Proteins of Enveloped Animal Viruses", Quarterly Review of Biophysics, 16(2):151-195 (1983)	
	ES	J. WHITE, "Membrane Fusion", Science, 258:917-924 (November, 1992)	
	ET	H. WILL et al, "Cloned HBV DNA Causes Hepatitis in Chimpanzees", Nature, 299:740-742 (October, 1982)	
	EU	W. WILLIAMS et al, "Restricted Heterogeneity of T Cell Receptor Transcripts in Rheumatoid Synovium", J. Clin. Invest., 90:326-333 (August, 1992)	
	EV	J. WILSON et al, "A Novel Mechanism for Achieving Transgene Persistence in Vivo After Somatic Gene Transfer into Hepatocytes", J. Biol. Chem., 267(16):11483-11489 (June, 1992)	
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	EX	G. WU et al, "Evidence for Targeted Gene Delivery to Hep G2 Hepatoma Cells in Vitro", Biochemistry, 27:887-892 (1988)		
	EY	G. WU et al, "Receptor-Mediated Gene Delivery and Expression in Vivo", J. Biol. Chem., 263(29):14621-14624 (October, 1988)		
	EZ	K. WUCHERPFENNIG et al, "Shared Human T Cell Receptor Vβ Usage to Immunodominant Regions of Myelin Basic Protein", Science, 248:1016-1019 (May, 1990)		
	EER	P. YEAGLE et al, "Effects of the 'Fusion Peptide' from Measles Virus on the Structure of N-methyl Dioleoylphosphatidylethanolamine Membranes and Their Fusion with Sendai Virus", Biochimica et Biophysica Acta., 1065:49-53 (1991)		
	EES	K. YOSHIMURA et al, "Adenovirus-Mediated Augmentation of Cell Transfection with Unmodified Plasmid Vectors", J. Biol. Chem., 268(4):2300-2303 (February, 1993)		
	EET	J. ZABNER et al, "Cellular and Molecular Barriers to Gene Transfer by a Cationic Lipid", J. Biol. Chem., 270(32):18997-19007 (August, 1995)		
	EEU	M. ZENKE et al, "Receptor-Mediated Endocytosis of Transferrin-Polycation Conjugates: An Efficient Way to Introduce DNA into Hematopoietic Cells", Proc. Natl. Acad. Sci. USA, 87:3655-3659 (May, 1990)		
	EEV	X. ZHOU et al, "DNA Transfection Mediated by Cationic Liposomes Containing Lipopolylysine: Characterization and Mechanism of Action, Biochimica et Biophysica Acta., 1189:195-203 (1994)		
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